K032243

OCT - 2 2003

5. 510(K) SUMMARY

5.1. Identification of Submitter

Predrag Sukovic, Ph.D.
President
Xoran Technologies, Inc
309 N. First Street
Ann Arbor, MI 48103

5.2. Identification of Product

Name	MiniCAT™
Manufacturer:	Xoran Technologies, Inc 309 N. First Street Ann Arbor, MI 48103
Distributor	Xoran Technologies, Inc 309 N. First Street Ann Arbor, MI 48103

5.3. Marketed Devices

The MiniCAT™ is substantially equivalent to the devices listed below:

Device	NewTom QR-DVT 900
Manufacturer	NIM s.r.l. Via Silverstrini, 20 37135 Verona Italy
510(k) Number	K003787
Device	Advantage 3-D XR
Manufacturer	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex France
510(k) Number	K945375
Device	3D Accu-I-tomo XYZ Slice View Tomograph
Manufacturer	J. Morita Manufacturing Corporation 680 Higashihama Minami-cho, Fushimi-ku Japan
510(k) Number	K030450

5.4. Device Description

The MiniCAT™ is a dedicated X-ray imaging device that acquires a 360° rotational X-ray sequence, reconstructs a three-dimensional matrix of the examined volume and produces two dimensional views of this volume. The MiniCAT™ can measure distances and thickness on two dimensional images. Images produced by the MiniCAT™ can be printed or exported on magnetic and optical media.

The building blocks of the MiniCAT™ are a motorized scanning arm carrying an X-ray source and image detector, and a computer running the MiniCAT™ software. The scanning arm facilitates the acquisition of a full X-ray sequence by the software. The software receives the two dimensional images acquired by the detector transforms them into three dimensional images and displays them on the computer monitor for viewing.

5.5. Intended Use

The MiniCAT™ is an X-ray imaging device that constructs a three dimensional model of the head and neck are from images taken during a rotational X-ray sequence. The MiniCAT™ is optimized for the imaging of the maxillofacial complex, temporal bone, sinuses, and for neuro-angiography.

5.6. Comparison with the Predicate Devices

The MiniCAT™ reconstructs a three dimensional model from X-ray images similar to the model obtained using the predicate devices. It displays either two-dimensional cross-sections or three dimensional views and allows the user to take measurements on the reconstructed images.

5.7. Conclusion

The MiniCAT™ acquires an X-ray rotational sequence and provides three-dimensional information on the analyzed volume. The potential hazards (e.g., electrical, mechanical, thermal, radiation, incorrect measurements, and misdiagnosis) are controlled by a risk management system including: Hazard Analysis and Software Development and Validation Process

The MiniCAT™ is an X-ray imaging system that complies with the requirements of 21 CFR 807.87(h) and does not pose any new safety risks or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Predrag Sukovic, Ph.D.
President
Xoran Technologies, Inc.
309 N. First Street
ANN ARBOR MI 48103

Re: K032243
Trade/Device Name: MiniCAT™
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: July 15, 2003
Received: July 29, 2003

Dear Dr. Sukovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033243

1. STATEMENT OF INDICATIONS FOR USE

The MiniCAT™ is an X-ray imaging device that constructs a three dimensional model of the head and neck are from images taken during a rotational X-ray sequence. The MiniCAT™ is optimized for the imaging of the maxillofacial complex, temporal bone, sinuses, and for neuro-angiography.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number